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§ 442.21 Cephaloglycin dihydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cephaloglycin dihydrate is the dihydrate form of 7-(D-α-aminophenylacetamido) cephalosporanic acid. It is a white to off-white powder. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms of cephaloglycin per milligram on an anhydrous basis.

(ii) [Reserved]

(iii) Its moisture is not less than 8.2 and not more than 12 percent.

(iv) Its pH in an aqueous suspension containing 50 milligrams per milliliter is not less than 3.0 and not more than 5.5.

(v) Its cephaloglycin content is not less than 95 and not more than 104 percent on an anhydrous basis.

(vi) It gives a positive identity test for cephaloglycin dihydrate.

(vii) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5(b) of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH, cephaloglycin content, identity, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed portion of the sample in sufficient sterile distilled water to give a stock solution of 100 micrograms of cephaloglycin per milliliter (estimated). Further dilute an aliquot of the stock solution with 0.1*M* potassium phosphate buffer, pH 4.5 (solution 4), to the reference concentration of 10 micrograms of cephaloglycin per milliliter (estimated).

(2) [Reserved]

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous suspension containing 50 milligrams per milliliter.

(5) *Cephaloglycin content.* Proceed as directed in § 436.213 of this chapter, using the titration procedure described in paragraph (e)(2) of that section. Calculate the cephaloglycin content as follows:

$$\text{Percent cephaloglycin content} = \frac{(A - B)\ (\text{normality of perchloric acid reagent})\ (405.4)\ (100)\ (100)}{(\text{Weight of sample in milligrams})\ (100 - m)}$$

where:

A=Milliliters of perchloric acid reagent used in titrating the sample;

B=Milliliters of perchloric acid reagent used in titrating the blank;

m=Percent moisture content of the sample.

(6) *Identity.* Proceed as directed in § 436.211 of this chapter, using the 0.5-percent potassium bromide disc prepared as described in paragraph (b)(1) of that section.

(7) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

[39 FR 19040, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 442.22a Sterile cefmenoxime hydrochloride.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefmenoxime hydrochloride is 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-3-[[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-, hydrochloride (2:1), [6*R*-[6α,7β(*Z*)]]-. It is so purified and dried that:

(i) Its cefmenoxime content is not less than 869 and not more than 1,015 micrograms of cefmenoxime per milligram on an anhydrous basis.

(ii) It is sterile.